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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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HARRIET M. STRIMPEL; NEW ENGLAND BIOLABS, INC.
240 COUNTY ROAD
IPSWICH, MA 01938-2723

EXAMINER	
COUNTS, GARY W	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,183	ZHANG ET AL.	
	Examiner	Art Unit	
	GARY W. COUNTS	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *18-22* is/are withdrawn from consideration.

5)☐ Claim(s) *14* is/are allowed.

6)☒ Claim(s) *1-13 and 15-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/22/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group I, claims 1-17 in the reply filed on November 27, 2007 is acknowledged.

Specification

2. The disclosure is objected to because of the following informalities: On page 6, line 16 of the specification the disclosure "Figure 2" should be deleted and replaced with --Figures 2 A-D--, to more accurately describe figures 2A-D.

3. On page 6, lines 5-6 after the disclosure Chitinase VP1, it appears that the recitation "Fig. 3-2" should be deleted and replaced with --Fig. 3-3--.

4. On page 13, line 6 it appears that the disclosure "CBPs" should be --CBD--. Appropriate correction is required.

5. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Sequence compliance

6. The specification lists amino acids sequences which are greater than four amino acids and does not provide a sequence identifier, paper copy or computer readable form for this sequence For example in the specification on page 7, line 15 applicant discloses a sequence "W-5-Y-12-5-H-7-P-S-L". However, there has been no CRF

submitted or paper copy of the "Sequence listing" nor is there a sequence identifier for this sequence.

Appropriate correction is required.

(1) The application clearly fails to comply with the requirement of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

(2) This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

(3) A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

Applicant must provide:

An initial or substitute computer readable from (CFR) copy of the "Sequence Listing".

An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

A statement that the content of the paper and computer readable copies are the same and, where applicable, include not new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or1.825(d).

The time for reply of the sequence compliance is set to the time of reply for the office action.

For questions regarding compliance to these requirements, please contact :

For Rules Interpretation, call (571) 272-2510
For CRF Submission Help, call (571) 272-2501/2583

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Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 7-9, 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 is confusing, vague and indefinite because it is unclear how claim 7 further limits claim 6. Claim 6 recites the addition of a second reagent comprising an antibody. However, claim 7 recites the first reagent comprises a reporter. The first reagent is recited in claim 1, thus it appears that claim 7 would only limit claim 1 and not claim 6. However, because claim 7 depends from claim 6 it is unclear how the limitation of claim 7 would further limit claim 6. Does applicant intend that the first reagent or the second reagent comprises the reporter. Further, claim 2 limits the first reagent conjugated to a reporter and thus it appears that claim 7 would be a duplicate of claim 2. Also, the specification on page 13 and page 15 disclose that the antibody is labeled when the antibody is specific for the chitin-binding domain. Please clarify.

Claim 9 is vague and indefinite because of the use of an acronym i.e. CBM12. Although the term may have art-recognized meaning, it is unclear if applicant intends to claim the prior art definition. The term should be defined in its first instance.

Claim 15 is vague and indefinite because of the use of an acronym i.e. MBP. Although the term may have art-recognized meaning, it is unclear if applicant intends to claim the prior art definition. The term should be defined in its first instance.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 9 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al (Expression and Characterization of the Chitin-Binding domain of Chitinase A1 from Bacillus circulans WL-12, Journal of Bacteriology, June 2000, p. 3045-3054).

Hashimoto et al disclose a method of detecting chitin in a sample. Hashimoto et al disclose contacting a reagent of chitin-binding domain with a sample containing chitin. Hashimoto et al disclose that the chitin-binding domain is $CHBD_{ChiA1}$ (p. 3047, p. 3048, p. 3051 & Figs. 1-3. Hashimoto et al disclose detecting the binding between the chitin-binding domain and the chitin. Hashimoto et al disclose that this chitin-binding domain bound only to chitin and that no significant binding to cellulose or other polysaccharides was detected (p. 3051, 2nd col). Hashimoto e al discloses that the binding domain was obtained from Chitinase a1 from Bacillus circulans (abstract, p. 3045).

With respect to claim 9 as indicated by applicant on page 10 of the specification, chitinase A1 contains CBD that belongs to CBM12. Thus, it is inherent that the CBD of Hosimoto et al has a carbohydrate-binding module corresponding to CBM12.

11. Claims 1-3 are rejected under 35 U.S.C. 102 (b) as being anticipated by Gray et al (US 6,399,571).

Gray et al disclose a method of detecting chitin in a sample. Gray et al disclose contacting the sample with a chitin-binding domain conjugated with a detectable label, such as a radioisotope, fluorophore, dye electron-dense compound or enzyme and measuring the amount of chitin in the sample (col 7, lines 45-63). Gray et al disclose that this chitin-binding domain is a chitin-specific reagent for specifically identifying the presence of chitin in the sample.

With respect to the recitation "whether chitin and not cellulose is present in the sample". This limitation is not given patentable weight because the recitation simply expresses the intended result of a process step positively recited. Gray et al recites every positive method step of contacting the sample and detecting specifically the binding of CBD to chitin and explicitly teaches that the chitin-binding domain is a specific reagent for chitin. Thus, Gray et al reads on the instantly recited claims.

12. Claims 12 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Idusogie et al (US 6,242,195).

Idusogie et al disclose an immobilized chitin-binding domain reagent (col 15, line 66 - col 16, line 8). Idusogie et al disclose that the reagent can be packaged into a kit

and that instructions for performing the assay can also be included in the kit (col 16, lines 34-59).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claims 1, 4, 5, 9, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuse et al (WO 92/17786) in view of Hashimoto et al (Expression and Characterization of the Chitin-Binding domain of Chitinase A1 from Bacillus circulans WL-12, Journal of Bacteriology, June 2000, p. 3045-3054).

Tuse et al disclose methods for detecting chitin. Tuse et al disclose chitinase reagents which specifically bind to chitin (p. 4). Tuse et al disclose contacting a sample with the chitinase and detecting chitin in the sample (e.g. p. 4, p. 10, Fig. 7). Tuse et al disclose that the enzyme (reagent) can be immobilized to a solid support and used to capture chitin and subsequently detected to determine the chitin or that the chitinase can be labeled with a reporter such as an enzyme and used to detect the chitin (Figure 6). Tuse et al also disclose that the sample can be mammalian and plant fluid and tissues or water (p. 5 and p. 9). Tuse et al also disclose packaging the components into a kit.

Tuse et al differ from the instant invention in failing to explicitly teach a chitin-binding domain.

Hashimoto et al disclose a chitin-binding domain $CHBD_{ChiA1}$ (p. 3047, p. 3048, p. 3051 & Figs. 1-3) used in binding assays to determine chitin in a sample. Hashimoto et al disclose that this chitin-binding domain binds only to chitin and not to cellulose or other polysaccharides (p. 3051, 2nd col). Hashimoto e al disclose that the binding domain was obtained from Chitinase a1 from Bacillus circulans (abstract, p. 3045).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute chitin-binding domain as taught by Hashimoto et al for

the chitinase of Tuse et al and to place the reagent into a kit because Hashimoto et al teaches that chitinase can bind to cellulose non-specifically and that the binding domain $CHBD_{ChiA1}$ binds only to chitin and not cellulose and one of ordinary skill in the art would recognize that this would provide for a decrease in non-specific binding of the reagents and thus increase assay sensitivity.

17. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuse et al (WO 92/17786) in view of Hashimoto et al and further in view of Gray et al (US 6,399,571).

See above for the teachings of Tuse et al and Gray et al.

Tuse et al and Gray et al differ from the instant invention in failing to specifically teach the chitin-binding domain comprises a reporter.

Gray et al teaches that it is known in the art to label chitin-binding domains with a reporter to detect chitin in a sample (col 7, lines 45-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a reporter such as taught by Gray et al into the modified method of Tuse et al because Tuse specifically teaches that the chitin specific reagent can be labeled for the detection of chitin (fig 6) and Gray et al teaches that it is conventional in the art to label chitin-binding domains to provide for reagents to detect chitin in a sample. Thus, one of ordinary skill in the art would have a reasonable expectation of success incorporating a label on the modified chitin-binding reagent of Tuse et al.

18. Claims 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuse et al (WO 92/17786) in view of Hashimoto et al and further in view of Gray et al (US 6,399,571).

See above for the teachings of Tuse et al and Gray et al.

Tuse et al and Gray et al differ from the instant invention in failing to specifically teach an antibody to chitin-binding domain.

Gray et al teach the use of antibodies that specifically bind to chitin-binding domains for detection of chitin-binding domain (col 6). Gray et al also teaches that it is known in the art to label chitin-binding domains with a reporter to detect chitin in a sample (col 7, lines 45-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate chitin-binding domain antibodies as taught by Gray et al into the modified method of Tuse et al because Tuse et al specifically teaches the use of a second reagent of antibodies for binding to the chitin-binding biological reagent (Fig 7) and one would use the appropriate reagent to detect the modified binding-reagent of Tuse and Hashimoto et al and Gray teaches that it is known in the art that chitin-binding domain antibodies specifically bind to chitin-binding domain.

With respect to claims 7 and 8 as currently recited. It would have also been obvious to one of ordinary skill in the art at the time the invention was made to incorporate a reporter such as taught by Gray et al into the modified method of Tuse et al because Tuse specifically teaches that the chitin specific reagent can be labeled for the detection of chitin (fig 6) and Gray et al teaches that it is conventional in the art to

label chitin-binding domains to provide for reagents to detect chitin in a sample. Thus, one of ordinary skill in the art would have a reasonable expectation of success incorporating a label on the modified chitin-binding reagent of Tuse et al. Further, because of the 112 2nd issues of claims 7 and 8 (see above) the combination of references is considered appropriate and thus reads on the instantly recited claims.

19. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tuse et al (WO 92/17786) and Hashimoto et al in view of Harman et al (US 6,251,390).

See above for the teachings of Tuse et al and Hashimoto et al.

Tuse et al and Hashimoto et al differ from the instant invention in failing to teach bleaching the sample.

Harman et al disclose that it is known in the art to bleach a sample of chitin which provides for purification of the chitin (col 3, lines 34-51).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to bleach the sample of Tuse et al because Haman et al teaches that it is known in the art to bleach samples of chitin in order to provide for purification of the chitin.

20. Claims 13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tuse et al (WO 92/17786) and Hashimoto et al in view of Foster et al (US 4,444,879)

See above for the teachings of Tuse et al and Hashimoto et al.

Tuse et al and Hashimoto et al differ from the instant invention in failing to teach instructions placed into the kit.

Foster et al disclose instructions (packaging material) packaged in a kit for using the kit (col 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate instructions as taught by Foster et al. into the modified kit of Tuse et al because Foster et al shows that instructions provide for the use of kits and one skilled in the art would recognize that the addition of instructions would make it more convenient and facile for the test operator.

21. Claims 14 is considered allowable over the prior art of record.

22. Claims 15 and 16 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The prior art of record does not teach or fairly suggest a kit comprising an immobilized chitin-binding domain (CBD) and further comprising a soluble CBD carrier protein fusion molecule linked to a reporter.

The closes prior art is attributed to Xu et al (7,001,745), Evans et al (US 7,271,256) and Chong et al., (Gene 192 (1997) 271-281) which teach chitin-binding domain fused with a carrier protein and used as affinity tags for purification. However, Xu et al., Evans et al., and Chong et al do not teach nor suggest that these fusion

proteins are labeled or packaged into a kit which already comprises an immobilized chitin-binding domain.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GARY W. COUNTS whose telephone number is (571)272-0817. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ Gary W. Counts/
Examiner, Art Unit 1641

/Long V Le/
Supervisory Patent Examiner, Art Unit 1641